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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/521,038

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EXAMINER

HOBBS, LISA JOE

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

01/06/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/521,038	Applicant(s) ROOS ET AL.	
	Examiner Lisa J. Hobbs	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38,41-47 and 50-62 is/are pending in the application.
- 4a) Of the above claim(s) 46,47,50-60 and 62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38,41-45 and 61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawings are accepted as amended in the submission of 26 July 2010.

Sequence Rules Compliance

The submission of a proper Sequence Listing and the amendments to the disclosure have placed the application in compliance with all sequence rules.

All objections and rejections of claims from the prior Non-Final Office Action, mailed 26 January 2010, which are not restated in the instant Final Office action are withdrawn as being corrected by or rendered moot by applicant's response filed 26 July 2010.

Claim Notes

The examiner notes that claims 43 and 45 refer to the first antibody of the detection complex. Is it possible that claim 45 should depend directly from claim 38, wherein said first antibody is labeled, to note that step (d) is detecting using a labeled antibody, as opposed to some other form of detection? Claim 43 could then depend from claim 38, wherein said first antibody is poly- or monoclonal, or from claim 45, wherein said first labeled antibody is poly- or monoclonal. This has not been made as a claim objection since it is merely a question of how applicant wants to denote that one option for detection is a labeled antibody.

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Claim Objections

Claim 62 is objected to because of the following informalities: although the claim is noted as “new” it is not noted also as “withdrawn”, which is should be since it depends from a claim that is currently not elected for examination. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 38, with dependent claims 41-45 and 61, is again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what applicant intends to claim with the language “physiological pH” and “physiological ion strength”. It is unclear what “physiological” means with reference to the limitations for the performance of this method since the method is in vitro and not limited to mammalian systems, buffers, etc. While mammalian samples are specified, the use of all reagents and compounds from a mammal is not specified. Also, included in the difficulty with the limitation “physiological” is the fact that not every body fluid from a mammal will possess the same elements and it is unclear which body fluids other than blood, serum, and plasma will possess the physical elements such as complement pathway factors and particular ions, etc., to facilitate the performance of the method as described. For example, page 15 of the specification refers to particular buffers that could be used, but cautions that high ionic strength buffers could cause problems and should be taken into account. The independent claim, and subsequent dependent claims, require further clarification.

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Claim 38, with dependent claims 41-45 and 61, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 38 part (b) refers to "inhibit the activation of an alternative pathway of complement". It is unclear if diluting the sample with buffer is known and expected to inhibit the activation of "any" or "all" alternative complement pathways or if some other factor in the sample at this point is inhibiting the other complement pathways or if there is only one other complement pathway other than lectin pathway. At this point in the claim, the lectin pathway has not been activated by the carbohydrate, thus it is unclear what "alternative pathway" is being inhibited and by what.

Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear which of the C1 complex inhibitor alternatives of claim 38 "said immunoglobulin" refers to. There is one group that is denoted as "an immunoglobulin that binds against C1q, C1r, or C1s", but it is not made clear if this immunoglobulin, which is a poly- or monoclonal antibody, is one of these choices or could be all three or could be one of the other alternative choices in part (a), such as any of the elements of the first grouping.

Claims 42 and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear which of the carbohydrates is the "said carbohydrate" denoted in the claim. There are two separate carbohydrates noted in claim 38 part (c), MBL and

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ficolin binding carbohydrate, if either of these or both of these may be mannose, fucose or mannan, and then glucomannan or galactomannan, then it should be made clear. If it is only MBL or ficolin binding carbohydrate that may be a range of carbohydrate, then that should be made clear.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa J. Hobbs whose telephone number is 571-272-3373. The examiner can normally be reached on Hotelling - Generally, 9-6 M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lisa J. Hobbs/
Primary Examiner
Art Unit 1657

ljh